REMARKS

This Amendment is in response to the Office Action mailed on December 5, 2007. Claim 37 has been amended. No Claims have been canceled or withdrawn. Thus, claims 1-46 are pending. Reconsideration of the above-identified application, in view of the above amendments and the following remarks, is respectfully requested.

Claims 15-17 and 34-36 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

Claims 15-17 and 34-36 stand rejected under 35 U.S.C. 112, second paragraph, being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner objects to Applicant's use "means for being ... powered" as being subject matter that was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention.

Applicant's respectfully disagree. "The law is clear that a patent application need not include subject matter that is known in the field of the invention and is in the prior art, for patents are written for persons experienced in the field of the invention." *S3 Inc. v. nVIDIA Corp.,* 259 F.3d 1364 (Fed. Cir. 2001)

The enablement requirement can be met by reference to the knowledge of one of ordinary skill in the relevant art. See *Bayer AG v. Schein Pharmaceuticals, Inc.*, 301 F. 3d 1306 (Fed. Cir. 2002). *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F. 2d 1367 (Fed. Cir. 1986), *cert. Denied;*, 480 U.S. 947 (1987) states that "[A] patent need not teach, and preferably omits, what is well known in the art."

Atmel Corp. Information Storage Devices, Inc., 198 F. 3d 1374 (Fed. Cir. 1999) states that a "'one skilled in the art' analysis should be applied in determining whether sufficient structure has been disclosed to support a means-plus-function limitation flows naturally from the relationship between claim construction and §112, ¶2."

Applicant in the originally filed specification that "CPU (20) preferably includes an antenna (28) for wireless communicating with an external device by telemetry in a manner known to those skilled in the art." (pg 4, l. 3-5) In addition, Applicant's state that the "CPU and sensors are preferably non-invasively powered by the external device using

RF telemetry." (pg 6, l. 16-17) Thus, Applicant's made it clear that using wireless communication to power a CPU and a sensor are known to those skilled in the art. Indeed, the following US Patents all teach powering an implant using RF telemetry:

- 5,735,887 Closed-Loop, RF-Coupled Implanted Medical Device (See Fig. 1 - RF transmitting inductor 34 (Col. 10, ll. 56-57) and RF receiving inductor 70 (Col. 11, ll. 20-21)
- 6,442,434 Method and Apparatus for Providing a Sufficiently Stable Power to a Load in an Energy Transfer System (See Fig. 2 - primary winding 32 and secondary winding 34. See also description of TET systems (Col. 1, line 24 through Col. 2, l. 13))
- 6,430,444 Transcutaneous Energy Transfer Device (See Figs. 2, 4, 5 - primary winding L1 and secondary winding L2 (Col. 4, ll. 40-51))
- 5,995,874 Transcutaneous Energy Transfer Device ((See Figs. 2, 4, 5 - primary winding L1 and secondary winding L2 (Col. 4, ll. 16-27))
- 5,755,748 Transcutaneous Energy Transfer Device ((See Figs. 2, 4, 5 - primary winding L1 and secondary winding L2 (Col. 4, ll. 30-40))
- 4,924,171 System for Supplying Power Source by Electromagnetic Induction Coupling (See Figs. 1, 3, 6 - induction coils 24-1 and 24-2 (Col. 4, ll. 4-20)
- 4,082,097 Multimode Recharging System for Living Tissue Stimulators (See Fig. 1. - external winding or coil 19 and pickup winding or coil 18 (Col. 4, ll. 34-46)
- 6,445,986 Implantable Medical Device (no figure per se, but see generic disclosure of TET implantable systems (Col. 1, ll. 9-21)

For at least these reasons, Applicant's maintain that the rejection of claims 15-17 and 34-36 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, and under 35 U.S.C. 112, second paragraph, for being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, should be withdrawn.

In addition, the specification also discloses at page 6, lines 18-27:

> However, the CPU and sensors may be non-invasively powered using optical or acoustical methods.

> The sensors could also directly communicate with the external device using acoustic waves, thereby eliminating the need of the CPU. Such sensors are currently available from Remon Medical Technologies, Ltd, 7 Halamish St, Caesaria Industrial Park, 38900, Israel. Alternatively, as one skilled in the art will recognize, the CPU and sensors may communicate with an external device using RF or optics. An example of an optical signal and energy transmission device is disclosed in Optical Signal and Energy Transmission for a Retina Implant, by M. Gross et al. and published in BMEW-EMBS 1st Joint conference, 1999, Atlanta, USA, the disclosure of which is hereby fully incorporated by reference in its entirety.

Thus, the original specification also clearly teaches powering the CPU and sensors using optical methods. An example of an optical signal and energy transmission device is disclosed and is incorporated by reference. Thus, for this additional reason the rejection of claims 15-17 and 34-36 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, and under 35 U.S.C. 112, second paragraph, for being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, should be withdrawn.

Claims 1-24, 38-44 and 46 stand rejected under 35 U.S.C. 103(a) as being unpatentable over US 65856777 to Cowan, Jr. et al in view of US 6248080 to Miesel et al.

The Examiner admits that Cowan fails to teach or suggest a pressure sensor upstream of the valve within the housing as required by claims 1-24 and 38-46. The Examiner states that Miesel discloses an intracranial monitoring device that may comprise several pressure sensors. This is true. However, the Examiner then asserts that Miesel suggests the addition of multiple pressure sensors around a treatment device to diagnose problems in the treatment device. The Examiner concludes that it would have been obvious "to merely duplicate the pressure sensor arrangement 52 downstream of the

valve 50 in order to diagnose valve performance." The Examiner bases this conclusion on the assumption that the "references reasonably suggest… an implantable medical device with pressure sensors disposed throughout the device that allow for accurate diagnosis and treatment of cerebral events, rendering the instantly claimed invention an unpatentably obvious variation of the prior art."

Applicant's respectfully disagree. Applicant's maintain that one of ordinary skill in the art would not have found it obvious to modify Cowan's device so that the upstream pressure sensor is located within the housing.

All of the independent claims of the present invention (claims 1, 18, 21, 24, 25 and 37-40) recite that the first and second pressure sensors are disposed within the housing along with the valve, or they recite that a differential pressure sensor is disposed in the housing with the valve. This is structure that is neither taught nor suggested by Cowan. Referring to Figs. 1 and 2 of Cowan, and the corresponding disclosure, the only housing illustrated and described is the master control unit 24. A valve gauge assembly 52, 52a is disclosed as being housed within the master control unit 24 (see, for example, col. 5, lines 12-13). Valve gauge assembly 52, 52a is disclosed as including a pressure gauge and a valve. Cowan does not disclose, however, if this pressure gauge is disposed upstream or downstream with respect to the valve. Cowan also discloses that a ventricular gauge 54 is located proximal to the ventricular catheter 32 and is connected to the portion of assembly 52 housed within master control unit 24 via a control line 56. The adjective "ventricular" refers to the ventricles of the brain. Ventricles are cavities in the brain that are filled with cerebrospinal fluid. It is precisely this fluid that is to be drained by Cowan's device. In practice, the valve housing is disposed outside of a patient's skull, and fluid communication with a patient's ventricles (obviously located within the skull) is achieved by way of a ventricular catheter. Thus, Cowan makes it abundantly clear that ventricular gauge 54 is disposed outside of the master control unit housing 24. Cowan also teaches that a control line 56 is used to connect gauge 54 and master control unit 24. Therefore, Cowan teaches away from including a second pressure sensor within the housing of master control unit 24.

Applicant's reviewed Miesel's disclosure in column 9, lines 20-67 and column 11, lines 40-65, but fail to see Miesel's suggestion of placing first and second pressure sensors within the housing along with the valve, which is what is presently claimed. In fact, Miesel is very similar to Cowan in that the sensor 20 is disposed in the brain at the distal end of lead 12. Miesel discloses that "[l]ead 12 may have mounted, attached thereto or incorporated therein one or more pressure sensors..." (column 9, lines 45-46). Miesel further discloses that "an integrated implantable medical device system of the present invention comprising IMD 100, external device 500, therapy delivery device 600, and one or more temperature and/or pressure sensor leads 12 implanted within or near the brain and connected to corresponding IMD 100, IMD 100 receiving and/or transmitting to external device 500 the signals sensed and generated by lead 12..." (column 11, lines 41-47). The Figures 1a-1d, and at least 2-6 all show the sensor(s) 20 located at the distal end of lead 12. Figure 1d also clearly shows the shunt 600 (i.e., the valve) located outside of the skull and as a separate element from lead 12 and sensor(s) 20. Figure 1d also clearly shows IMD 100 located further downstream, or away from the brain. Thus, just as in Cowan, Miesel also teaches away from including a second pressure sensor within the housing of master control unit 24. In fact, Miesel teaches away from placing any pressure sensors whatsoever within a CPU housing.

Cowan teaches in column 4, lines 14-23, that "master control unit 24 is powered by a battery 36" such as those widely used in pacemakers, stimulators, defibrillators and the like. Despite the knowledge of those skilled in the art at the time of Cowan's invention regarding externally powering an implanted device, Cowan makes no mention or suggestion that his device can be powered non-invasively. Miesel teaches in column 9, lines 21-23 that IMD 100 contains a battery to power lead 12. Thus, claims 15-17 which recite that the CPU has means for being powered non-invasively (not a means for calculating as the Examiner states) is not taught or suggested by the combination of Cowan and Miesel.

Claims 25-30 and 34-37 stand rejected under 35 U.S.C. 103(a) as being unpatentable over US 6585677 to Cowan, Jr. et al in view of US 4206762 to Cosman.

The Examiner admits that Cowan fails to disclose the pressure sensor 52 comprises a differential pressure sensor. The Examiner is relying on Cosman for the teaching of an implantable differential pressure sensor. The Examiner concludes that one of ordinary skill in the art would have found it obvious to substitute Cosman's differential pressure sensor for Cowan's pressure sensor. However, the question arises as to where one skilled in the art would have placed the differential pressure sensor in Cowan's modified device. Applicant's maintain that one skilled in the art would have substituted the differential pressure sensor for Cowan's for ventricular guage 54. This is because for Cosman's sensor to work CSF must be disposed on one side of the membrane. The only guage that is disposed within the brain and therefore could have access to CSF is Cowan's guage 54. Thus, substituting a differential pressure sensor for Cowan's guage 54 does not result in the CPU and the differential pressure sensor being disposed in the same housing, as required by claims 25-30 and 34-37.

Applicant's note that to utilize differential pressure sensor, as illustrated in Figures 5 and 6, Applicant utilize a fluid conduit 52 to expose one side of membrane 50 to fluid pressure upstream of the valve. If the Examiner proposes to use a similar structure so that a differential pressure sensor can be substituted for Cowan's valve guage assembly 52, 52a, Applicant's maintain that the Examiner is clearly using impermissible hindsight.

Thus, claims 25-30 and 34-37 are not suggested by the combination of Cowan and Cosman.

Claims 31-33 stand rejected under 35 U.S.C. 103(a) as being unpatentable over US 6585677 to Cowan, Jr. et al in view of US 4206762 to Cosman, further in view of US6248080 to Miesel.

The remaining rejections of the pending dependent claims, including claims 313-33, should become moot in view of the fact that independent claims are allowable. Thus, a Notice of Allowance in response to this Amendment is respectfully requested.

Please provide any extensions of time which may be necessary and charge any fees which may be due to Deposit Account No. 10-0750.

Should there be any remaining or further questions, the Examiner is requested to place contact the undersigned directly.

Respectfully submitted,

/Eugene L. Szczecina, Jr./

Eugene L. Szczecina, Jr.
Attorney for Applicants
Reg. No. 35,029
Johnson & Johnson
1 Johnson & Johnson Plaza
New Brunswick, NJ
(732) 524-1479

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